PATENT COOPERATION TREATY

To:

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WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing *(day/month/year)*	14 April 2005 (14.04.2005)
Applicant's or agent's file reference: HDL-PCT-25	**FOR FURTHER ACTION** See paragraph 2 below
International application No.: PCT/IN 2004/000337	International filing date *(day/month/year)*: 1 November 2004 (01.11.2004)
	Priority Date *(day/month/year)*: ----------
International Patent Classification (IPC) or both national classification and IPC: C07D 501/04, 501/22	
Applicant: HETERO DRUGS LIMITED	

1. This opinion contains indications relating to the following items:

- [x] Cont. No. I — Basis of the opinion
- [ ] Cont. No. II — Priority
- [ ] Cont. No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- [ ] Cont. No. IV — Lack of unity of invention
- [x] Cont. No. V — Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- [ ] Cont. No. VI — Certain documents cited
- [ ] Cont. No. VII — Certain defects in the international application
- [ ] Cont. No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/IN 2004/000337

Continuation No. I

Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed.

Continuation No. V

Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims **1-13**	**YES**
	Claims **----**	**NO**
Inventive step (IS)	Claims **1-13**	**YES**
	Claims **----**	**NO**
Industrial applicability (IA)	Claims **1-13**	**YES**
	Claims **----**	**NO**

2. Citations and explanations:

All documents cited in the Search Report are referred to in this communication.

In the light of these prior art documents the subject matter of the present application appears to be novel and inventive, since:

- a silylated mixed anhydride of formula II according to the present application has not been specified in prior art so far or disclosed generically and

- there could not be derived any suggestion from the (combined) teachings of the cited documents that

a) by the use of the novel intermediate of formula II the cephalosporin compound Cefprozil could be prepared without the need of isolation of intermediates and that

b) the use of the silyl protected compound of formula II avoids the self acylation of the mixed anhydride used as an intermediate in the preparation of Cefprozil and thus allows the preparation of Cefprozil without strict control of quantity of the silyl protected intermediate and without controlled addition of the reactant.

Industrial applicability is given.